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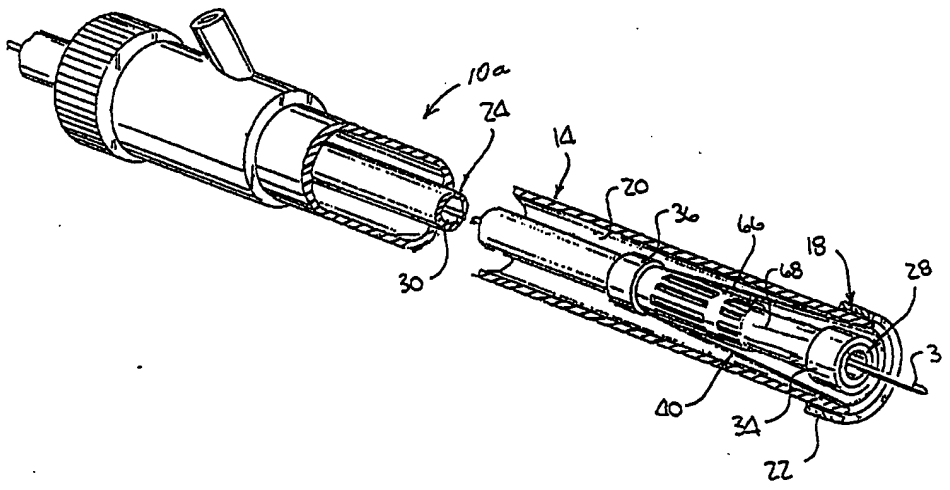

(57) Abstract

The present invention is a delivery catheter (10) for a radially expandable intraluminal stent (12). The delivery catheter comprises an elongate outer tube (14) defining proximal, distal ends, and a lumen (20) extending longitudinally therethrough. In addition to the outer tube the delivery catheter includes an elongate inner tube (24) defining proximal, distal ends, and a guide wire lumen (30) extending longitudinally therethrough. The inner tube is movably disposed within the lumen of the outer tube. The delivery catheter further includes a flexible deployment sleeve (40) having a first end attached to the distal end of the outer tube, and a second end attached to the inner tube at a location proximal to the distal end thereof. The pressurization of the lumen of the outer tube with a fluid causes fluid pressure to be exerted on the sleeve in a manner facilitating the movement, and the inner and outer tubes relative to each other such that a distal portion of the inner tube extending distally from the second end of the sleeve is deployed from the distal end of the outer tube.

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RADIALLY EXPANDABLE INTRALUMINAL STENT AND DELIVERY CATHETER THEREFOR

Field of the Invention

The present invention pertains generally to medical devices, and more particularly to a radially expandable intraluminal stent device and delivery catheter therefore.

Background of the Invention

The term "stent" is generally used to describe endoprosthetic medical devices which are implanted in anatomical passageways (e.g., blood vessels, gastrointestinal tract, genitourinary tract, endocrine ducts, etc...) of the body for the purpose of maintaining the patency or state of dilation of the passageway, reinforcing the passageway, or anchoring a tubular graft or other object within the passageway.

In many applications, such stents are implanted in blood vessels to maintain dilation and patency of an occluded region of blood vessel, or to hold in place a tubular endoluminal graft which forms a conduit through a weakened or aneurysmic segment of a blood vessel. Typical non-vascular applications of such stents are for dilating and maintaining patency of constricted or stenotic regions of the gastrointestinal tract (e.g., esophagus), ducts of the biliary tree (e.g., common bile duct) or anatomical passageways of the genitourinary tract (e.g., ureter, urethra fallopian tube, etc.).

Transluminally implantable stents are typically of radially expandable construction such that they may be initially disposed in a compact configuration of relatively small diameter upon or within a delivery catheter to facilitate insertion and transluminal advancement of the stent into the desired anatomical passageway. Thereafter, such stents are radially

expanded to an expanded configuration having a larger diameter which is equal to or slightly larger than the diameter of the anatomical passageway in which the stent is implanted. When radially expanded to such larger diameter, the stent will typically become released or separated from the delivery catheter, and will become attached or frictionally engaged to the surrounding wall of the anatomical passageway.

Some stents are combined or associated with a pliable, continuous tubular covering, in which case they are typically referred to as a "stented graft" or "stent-graft".

In general, these intraluminal apparatus (i.e., stents, stented grafts, etc.) fall into two major categories -- a) self-expanding and b) pressure-expandable. Those of the self-expanding variety may be formed of resilient or shape memory material (e.g., spring steel or nitinol™) which is capable of self-expanding from its first (radially compact) diameter to its second (operative) diameter without the exertion of outwardly-directed force against the stent or stented graft. Examples of such self-expanding stents and stented grafts are set forth in United States Patent Nos. 4,655,771 (Wallsten, et al); 4,954,126 (Wallsten); 5,061,275 (Wallsten, et al); 4,580,568 (Gianturco); 4,830,003 (Wolf, et al); 5,035,706 (Gianturco, et al); 5,330,400 (Song) and 5,354,308 (Simon, et al) and Foreign Patent Publication Nos. WO94\12136; WO92\06734 and EPA183372. Those of the pressure-expandable (i.e., "passive expandable") variety may be formed of plasmically deformable material (e.g., stainless steel) which is initially formed in its first (radially compact) diameter and remains stable in such first diameter until such time outwardly directed pressure is exerted upon the stent or stented graft to cause radial expansion and resultant plastic deformation of the stent or stented graft, to its second (operative) diameter. Examples of

such pressure-expandable stents and stented grafts are set forth in United States Patent Nos.5,135,536 (Hillstead); 5,161,547 (Tower); 5,292,331 (Boneau); 5,304,200 (Spaulding); 4,733,665 (Palmaz); 5,282,823 (Schwartz, et al); 4,776,337 (Palmaz); and 5,403,341 (Solar) and Foreign Patent Publication Nos. EPA480667; and WO95\08966.

In many applications, careful positioning and sound anchoring of the stent or stented graft is critical to the successful treatment of the underlying medical problem. In this regard, the delivery catheter which is utilized to insert and position the stent or stented graft may be an important aspect of the overall system. Various types of delivery catheters for stents and stented grafts have been previously known, including those described in United States Patent Nos. 4,665,918 (Garza, et al); 4,733,665 (Palmaz); 4,739,762 (Palmaz); 4,762,125 (Leiman, et al);,776,337 (Palmaz); 4,838,269 (Robinson, et al); 4,994,071 (MacGregor); 5,037,427 (Harada, et al); 5,089,005 (Harada); 5,102,417 (Palmaz); 5,108,416 (Ryan, et al); 5,141,498 (Christian); 5,181,920 (Mueller, et al); 5,195,984 (Schatz); 5,201,901 (Harada, et al); 5,269,763 (Boehmer, et al); 5,275,622 (Lazarus, et al); 5,290,295 (Querals, et al); 5,306,294 (Winston, et al); 5,318,588 (Horzewski, et al); 5,344,426 (Lau, et al); 5,350,363 (Goode, et al); 5,360,401 (Turnland); 5,391,172 (Williams, et al); 5,397,345 (Lazarus); 5,405,380 (Gianotti, et al); 5,443,452 (Hart, et al); 5,453,090 (Martinez, et al); 5,456,284 (Ryan, et al); and 5,456,694 (Marin, et al) and Foreign Patent Publication Nos. EP-0308-815-A2; EP-0335-341-A1; EP-364-787-A; EP-0442-657-A2; EP-482976-A; EP-0505-686-A1; EP-0611-556-A1; EP-0638-290-A1; WO94\15549; WO95\01761; GB2196-857-A; DE3042-229; and DE3737-121-A.

None of the previously-known delivery catheter systems have been clearly optimal for all types of stents and stented grafts. Accordingly, there remains a need in

the art for a design and development of improved delivery catheter systems for at least some types of stents and stented grafts.

Summary of the Invention

In accordance with the present invention, there is provided a delivery catheter for transluminally delivering a radially expandable intraluminal apparatus (e.g., a stent, stented graft, etc.) to a desired location within a body lumen (e.g., a blood vessel, gastro-intestinal tract, duct, urethra, fallopian tube, etc.). The delivery catheter generally comprises an:

INSERT THE INDENTED ELEMENTS OF CLAIM 1 HERE

In some embodiments, the outer tube of the delivery catheter will be of fixed length and the inner tube will be of variable length, such that when the pressure within the lumen of the outer tube is increased, the inner tube will become longitudinally elongated and the flexible deployment sleeve will evert, thereby causing the delivery catheter to assume its second configuration as defined hereabove. Conversely, when the pressure within the lumen of the outer tube is decreased, the inner tube will shorten and the flexible sleeve will invert, thereby causing the delivery catheter to assume its second configuration as defined hereabove.

In other embodiments, the outer tube of the delivery catheter is of variable length and the inner tube is of fixed length, with the proximal end of the inner tube being attached to the body of the outer tube, such that when the pressure within the lumen of the outer tube is decreased, the outer tube will shorten and the flexible deployment sleeve will evert, thereby causing the delivery catheter to assume its second configuration as defined hereabove. Conversely, when the pressure within the lumen of the outer tube is increased, the outer tube will lengthen and the flexible deployment sleeve will invert, thereby causing the delivery catheter to assume its second configuration as defined hereabove.

Radio dense or radio opaque markers may be formed on the inner and/or outer tubes at locations which mark the opposite ends of the intraluminal apparatus (e.g., stent, stented graft, etc.) as it is mounted on the distal portion of the inner tube of the delivery catheter, thereby facilitating precise positioning of the intraluminal apparatus (e.g., stent, stented graft, etc.) prior to radial expansion and implantation thereof.

In some applications, the delivery catheter of the present invention may be used in combination with a self-expanding, implantable intraluminal apparatus (i.e., stent, stented graft, etc.) positioned on the distal portion of the inner tube. In other applications, the delivery catheter may be used in combination with a pressure-expandable, implantable intraluminal apparatus (e.g., stent, stented graft, etc.) which is positioned on an inflatable balloon or other pressure-exerting expansion member mounted or formed on the outer surface of the distal portion of the inner tube.

The delivery catheter of the present invention may be provided with a proximal connector assembly attached to the proximal ends of the inner and outer tubes. Such proximal connector assembly may comprise a tubular outer body which defines proximal and distal ends, with the proximal end of the outer tube being attached to the distal end of the outer body. Rotatably connected to the proximal end of the outer body is a knob member. In addition to the outer body, the proximal connector assembly may include a tubular inner body which defines proximal and distal ends, with the inner body extending through the knob member and into the interior of the outer body. The proximal end of the inner tube is itself attached to the distal end of the inner body. Disposed between the inner and outer bodies of the proximal connector assembly is an elastically deformable sealing member. The knob member is cooperatively engaged to the sealing member such that the rotation of the knob member

in a first direction causes compressive pressure to be applied to the inner body by the sealing member which prevents the movement of the inner and outer tubes relative to each other. Conversely, the rotation of the knob member in a second direction opposite the first direction discontinues the application of compressive pressure to the inner body by the sealing member which permits the movement of the inner and outer tubes relative to each other. The outer body of the proximal connector assembly further includes a tubular side arm portion which fluidly communicates with the lumen of the outer tube.

In accordance with a first embodiment of the invention, the outer tube may incorporate a longitudinally extendable/retractable region (e.g., a telescoping segment, a collapsible/extendable segment/ etc.) such that, when the lumen of the outer tube is unpressurized, the flexible sleeve will be inverted into the lumen of the outer tube and the inner tube will assume a longitudinally shortened configuration. Thereafter, when the lumen of the outer tube is pressurized, the flexible sleeve will assume an everted position and the inner tube will become elongated such that a distal portion of the inner tube upon which the intraluminal prosthesis (e.g., stent, stented graft, etc.) is mounted will extend out of and beyond the distal end of the outer tube. Thereafter, after the intraluminal prosthesis (stent, stented graft, etc.) has been implanted, the pressure within the lumen of the outer tube may be decreased so as to once again cause the flexible sleeve to become inverted within the lumen of the outer tube with the inner tube assuming its longitudinally shortened configuration.

In accordance with a second embodiment of the invention, the outer tube may incorporate a longitudinally extendable/retractable region (e.g., a telescoping segment, collapsible segment, etc.) and the

inner tube may be of fixed length such that when the lumen of the outer tube is pressurized, the outer tube will assume a longitudinally lengthened state such that the flexible sleeve and the entirety of the inner tube are contained within the lumen of the outer tube. Thereafter, when the pressure within the outer tube is decreased, the longitudinally extendable/retractable segment of the outer tube will assume a longitudinally shortened configuration thereby causing the distal end of the outer tube to retract such that the flexible sleeve and a distal portion of the inner tube upon which the intraluminal prosthesis (e.g., stent, stented graft, etc.) is mounted will become exposed or uncovered.

Further in accordance with the present invention, there is provided a method of delivering a radially expandable intraluminal prosthesis (e.g., stent, stented graft, etc.) to a desired intraluminal site. The method comprises the initial step of a) providing a delivery catheter which comprises the above-described inner tube, outer tube, and flexible deployment sleeve, with the delivery catheter further including the radially expandable intraluminal prosthesis positioned on the distal portion of the inner tube. Thereafter, b) the inner tube is advanced over a guide wire until such time as the distal end of the outer tube is positioned adjacent to the treatment site. Thereafter, c) the pressure within the lumen at the outer tube is changed so as to cause either i) the distal portion of the inner tube having the stent positioned thereon to be advanced out of and beyond the distal end of the outer tube or ii) the distal end of the outer tube to retract so as to expose the distal portion of the inner tube on which the intraluminal prosthesis (e.g., stent, stented graft, etc.) is mounted. After the prosthesis has been implanted, the distal portion of the inner tube may be re-positioned within the lumen of the outer tube and the entire delivery catheter is withdrawn. In the event the

delivery catheter is adapted for use with a pressure-expandable intraluminal prosthesis (i.e., stent, stented, graft, etc.) rather than a self-expanding intraluminal prosthesis (i.e., stent, stented graft, etc.), the catheter will typically include an inflatable balloon located on the outer surface of the distal portion of the inner tube, such balloon being inflatable subsequent to and separately from the pressurization of the lumen of the outer tube, to facilitate the radial expansion of a pressure expandable intraluminal prosthesis (i.e., stent, stented graft, etc.) positioned thereupon.

Brief Description of the Drawings

These, as well as other features of the present invention, will become more apparent upon reference to the drawings wherein:

Figure 1 is a perspective view of the delivery catheter for a radially expandable intraluminal stent constructed in accordance with the present invention;

Figure 2 is a partial longitudinal-sectional view of the delivery catheter of the present invention;

Figure 3 is a longitudinal-sectional view of the distal portion of the delivery catheter of the present invention, disposed in an initial configuration wherein a radially expandable stent is contained within the delivery catheter;

Figure 4 is a longitudinal-sectional view of the distal portion of the delivery catheter of the present invention, illustrating the manner in which a self-expanding stent is deployed from the distal end thereof;

Figure 4a is a longitudinal-sectional view of the distal portion of the delivery catheter of the present invention, illustrating the manner in which

a pressure-expandable stent is deployed from the distal end thereof;

Figure 5 is a longitudinal-sectional view of a proximal connector assembly which may be mounted on the proximal end of the delivery catheter of the present invention;

Figure 6 is a partial longitudinal-sectional view of an embodiment of the delivery catheter having a longitudinally elongateable/retractable inner tube;

Figure 6a is a partial longitudinal-sectional view of an alternative mode of construction of the inner tube of the embodiment shown in Figure 6;

Figure 7 is a top plan view of a particular self-expanding stent of the present invention, which may be utilized in conjunction with the delivery catheter of the present invention; and

Figure 7a is a perspective view of the self-expanding stent shown in Figure 7 in its operative, rolled configuration for positioning upon the delivery catheter of the present invention.

Figure 8a is a longitudinal-sectional view of a distal portion of an alternative embodiment of the delivery catheter having a longitudinally elongateable/retractable outer tube, disposed in an initial configuration wherein the radially expandable stent is contained within the lumen of the outer tube;

Figure 8b is a longitudinal-sectional view of the delivery catheter of Figure 8a, disposed in a deployment configuration wherein the stent is exposed and located outside of the outer tube.

Detailed Description of the Preferred Embodiments

Referring now to the drawings wherein the showings are for purposes of illustrating preferred embodiments of the invention only, and not for purposes of limiting the

scope of the invention in any way, Figure 1 illustrates a delivery catheter 10 which is usable for positioning a radially expandable intraluminal prosthesis (e.g., stent, stented graft, etc.) at a desired treatment site (e.g., a stenosis) within a blood vessel or other anatomical passageway. As will be discussed in more detail below, the preferred construction of the delivery catheter 10 allows for a relatively small diameter, thus facilitating advancement of the delivery catheter 10 through tortuous and/or small diameter anatomical passageways. Radially expandable vascular stents or stented grafts of various designs may be used in conjunction with the delivery catheter 10 of the present invention, including self-expanding stents, balloon expandable stents, or stents which are expandable by other means, such as stents fabricated from shape-memory materials which undergo radial expansion when warmed to body temperature.

In the preferred embodiment of the present invention, the delivery catheter 10 is used in conjunction with a self-expanding stent 12 (as shown in Figures 7 and 7a), the precise structure of which will be discussed in more detail below.

Referring now to Figures 1-3, the delivery catheter 10 comprises an elongate, flexible outer tube 14 which defines a proximal end 16 and a distal end 18. Extending longitudinally through the outer tube 14 is a lumen 20 which is defined by an inner luminal surface of the outer tube 14. Rigidly attached to the outer surface of the outer tube 14 is an annular radiopaque marker 22, the distal edge of which is substantially flush with the distal end 18 of the outer tube 14.

In addition to the outer tube 14, the delivery catheter 10 comprises an elongate, flexible inner tube 24 which itself defines a proximal end 26 and a distal end 28. Extending longitudinally through the inner tube 24 is guide wire lumen 30 which is defined by the inner luminal surface of the inner tube 24 and is adapted to

accommodate an elongate guide wire 32. As will be discussed in more detail below, the delivery catheter 10 is preferably constructed in one of two general embodiments, the first of which is shown in Figures 5-6a (having an inner tube 24a, 24b of longitudinally elongateable/retractable construction and the second of which is shown in Figures 8a-8b (having an outer tube 14a of longitudinally elongateable/retractable construction). The showings of Figures 1-5 are applicable to both of the embodiments shown in Figures 6-6a and 8a-8b, respectively. Also, Figures 7-7a show a specific roll-up stent device 12 which is configured and constructed in accordance with the present invention. This roll-up stent device 12 is one of many radially expandable intraluminal prostheses (e.g., stents, stented graft, etc.) which are usable in conjunction with the delivery catheter 10 of the present invention.

As seen in Figures 2-4, attached to the outer surface of the inner tube 24 is an annular, distal radiopaque marker 34, the distal edge of which is substantially flush with the distal end 28 of the inner tube 24. In addition to the distal radiopaque marker 34, also attached to the outer surface of the inner tube 24 at a location proximal to the distal end 28 is an annular, proximal radiopaque marker 36. In the delivery catheter 10, a distal portion 38 of the inner tube 24 is defined between the distal and proximal radiopaque markers 34, 36. As will also be described in more detail below, the distal portion 38 of the inner tube 24 is adapted to have a vascular stent (e.g., the stent 12) positioned thereupon for deployment into a desired treatment site.

The delivery catheter 10 constructed in accordance with the preferred embodiment of the present invention further comprises a flexible deployment sleeve 40 having a first end 42 which is attached to the outer tube 14 and a second end 44 which attached to the inner tube 24.

More particularly, the first end 42 of the sleeve 40 is rigidly captured between the radiopaque marker 22 and the outer surface of the outer tube 14, with the second end 44 of the sleeve 40 being rigidly captured between the proximal radiopaque marker 36 and the outer surface of the inner tube 24. Alternatively, outer tube 14 and sleeve 40 may be made from one piece, e.g., by thinning and/or expanding the distal segment of outer tube 14 to form sleeve 40.

Referring now to Figure 5, attached to the proximal ends 16, 26 of the outer and inner tubes 14, 24 is a proximal connector assembly 46. In the preferred embodiment, the proximal connector assembly 46 comprises a tubular outer body 48 having a proximal end 50, a distal end 52 and an inner surface which defines an interior chamber 54. The proximal portion of the inner surface of the outer body 48 is internally threaded to facilitate the threadable engagement of a knob member 56 to the proximal end 50 of the outer body 48. In the delivery catheter 10, the proximal end 16 of the outer tube 14 is rigidly attached to the distal end 52 of the outer body 48. More particularly, a proximal portion of the outer surface of the outer tube 14 is rigidly secured to a distal portion of the inner surface of the outer body 48. The attachment of the outer tube 14 to the outer body 48 is preferably facilitated through the use of an adhesive, though other bonding techniques may also be employed in the delivery catheter 10. When the outer tube 14 is attached to the outer body 48, the lumen 20 fluidly communicates with the interior chamber 54. The outer body 48 further includes an integral tubular side arm portion 58 which also fluidly communicates with the interior chamber 54, and hence the lumen 20 of the outer tube 14.

The proximal connector assembly 46 of the delivery catheter 10 further comprises a tubular inner body 60 which defines a proximal end and a distal end 62. The

inner body 60 is extended through a passage extending axially through the knob member 56, such that the distal end 62 thereof resides within the interior chamber 54 of the outer body 48. The proximal end 26 of the inner tube 24 is rigidly attached to the distal end 62 of the inner body 60. More particularly, a proximal portion of the outer surface of the inner tube 24 is rigidly secured to a distal portion of the inner surface of the inner body 60. The attachment of the inner tube 24 to the inner body 60 is also preferably facilitated through the use of an adhesive, though alternative bonding techniques may also be employed in the delivery catheter 10.

In addition to the aforementioned structural components, the proximal connector assembly 46 further includes an elastically deformable sealing member 64 which is disposed and captured between the inner surface of the outer body 48 and the outer surface of the inner body 60. The sealing member 64 preferably comprises a O-ring which is compressible, and fabricated from a lubricous material. When captured between the outer and inner bodies 48, 60, the sealing member 64 creates a fluid-tight seal therebetween, thus preventing the escape of any fluid within the interior chamber 54 from the proximal end 50 of the outer body 48 (i.e., from between the outer body 48 and knob member 56).

In the proximal connector assembly 46, the distal end of the knob member 56 is cooperatively engaged to the sealing member 64 such that the tightening of the knob member 56 (i.e., the rotation of the knob member 56 in a clockwise direction) facilitates the compression of the sealing member 64. The compression of the sealing member 64 causes compressive pressure to be applied to the inner body 60 thereby, thus preventing any movement of the outer and inner tubes 14, 24 relative to each other. In this respect, since the outer tube 14 is attached to the outer body 48 and the inner tube 24 to the inner body 60, maintaining the inner body 60 in fixed relation to the

outer body 48 by the compression of the sealing member 64 likewise maintains the outer and inner tubes 14, 24 in fixed relation to each other. Conversely, the loosening of the knob member 56 (i.e., the rotation of the knob member 56 in a counter-clockwise direction) discontinues the application of compressive pressure to the inner body 60 by the sealing member 64, thus permitting the movement of the outer and inner tubes 14, 24 relative to each other. Because compressive pressure is applied thereto, the inner body 60 is preferably of rigid construction so as to resist crushing or collapse when the sealing member 64 is compressed thereagainst. In this respect, the inner body 60 is preferably fabricated from a metal material, though other suitable rigid materials may also be used as an alternative to metal.

Referring now to Figures 3 and 4, the delivery catheter 10 may be used to deliver and implant a self-expanding stent, such as the particular roll-up stent 12 shown in Figures 7 and 7a. The delivery catheter 10 is used to deploy the stent 12 into a treatment site by initially positioning the rolled stent 12 upon the distal portion 38 of the inner tube 24. Subsequent to mounting of the stent 12 on the distal portion 38 of the inner tube, the distal portion 38 of the inner tube 24 (having the stent 12 mounted thereon) is wholly positioned within the lumen 20 of the outer tube 14. The positioning of the distal portion 38 within the lumen 20 is facilitated by loosening the knob member 56 of the proximal connector assembly 46. When the distal portion 38 (having the stent 12 positioned thereupon) is fully positioned within the lumen 20, the sleeve 40 is proximally stretched between the outer and inner tubes 14, 24, with the distal radiopaque marker of the inner tube 24 being concentrically positioned relative to the radiopaque marker 22 of the outer tube 14. Additionally, an annular, conically shaped space is defined between the

sleeve 40 and the inner luminal surface of the outer tube 14.

After the distal portion 38 has been positioned within the lumen 20, the knob member 56 of the proximal connector assembly 46 is re-tightened, thus preventing any movement of either of the outer or inner tubes 14, 24 relative to the other.

The inner tube 24 of the delivery catheter 10 is then advanced over the intraluminally positioned guide wire 32 which is extended into the guide wire lumen 30 of the inner tube 24. This allows the delivery catheter 10 to be advanced over the pre-inserted guide wire 32 until such time as the distal end 18 of the outer tube 14 is disposed at a desired location relative to the side at which the stent 12 is to be implanted. The distal end 18 of the outer tube 14 is precisely positionable relative to the implantation site, due to the presence of the radiopaque marker 22 thereon. As will be recognized, due to the knob member 56 of the proximal connector assembly 46 being tightened, the outer and inner tubes 14, 24 may be advanced as a unit over the guide wire 32.

As best seen in Figure 4, subsequent to the placement of the distal end 18 of the outer tube 14 at the desired location relative to the implantation site, the knob member 56 of the proximal connector assembly 46 is once again loosened so as to allow for axial movement of one of the outer or inner tubes 14, 24 relative to the other. The lumen 20 of the outer tube 14 is then pressurized with a fluid (e.g., sterile saline or contrast media) via the side arm portion 58 of the outer body 48 of the proximal connector assembly 46. The fluid flows into the space defined between the sleeve 40 and the inner luminal surface of the outer tube 14, with fluid pressure being exerted distally against the sleeve 40.

The application of such distally directed fluid pressure against the sleeve 40 results in either i)

distally directed longitudinal advancement of the distal portion 38 of the inner tube 14 from the distal end 18 of the outer tube 14 with concomitant eversion of the flexible sleeve 40 (see Figures 6 and 7) or ii) proximally directed longitudinal retraction of the distal portion of the outer tube 14 with concomitant eversion of the flexible sleeve 40 so as to uncover and expose the distal portion 38 of the inner tube 14. In this respect, with the knob member 56 being loosened, the outer body 48 of the proximal connector assembly 46 is tightly grasped as the lumen 20 is pressurized with the fluid, thus allowing for elongation of the inner tube 24 relative to the outer tube 14, or shortening of the outer tube 14 relative to the inner tube 24. As will be recognized, once the radiopaque markers 22, 36 are concentrically oriented relative to each other, the stent 12 positioned upon the distal portion 38 is completely uncovered and is no longer surrounded by the lumen 20 of the outer tube 14.

In applications where the sent 12 is of the self-expanding variety, the stent 12 will undergo immediate radial expansion into engagement with the luminal surface of the anatomical passageway upon being removed from within the lumen 20 of the outer tube 14 in the aforementioned manner. Reference to the radiopaque markers 22, 34, 36 allows for confirmation of the proper orientation of the stent 12 relative to the treatment site. Subsequent to the deployment of the stent 12, the distal portion 38 of the inner tube 24 is proximally drawn back into the lumen 20 of the outer tube 14 by pulling the inner body 60 of the proximal connector assembly 46 in the aforementioned manner. Thereafter, the knob member 56 of the proximal connector assembly 46 is re-tightened, with the delivery catheter 10 then being withdrawn from over the guide wire 32.

In other applications, as specifically shown in Figure 4a, the delivery catheter 10 of the present

invention may be used in conjunction with a pressure-expandable stent 66 rather than with the self-expanding stent 12. When the delivery catheter 10 is used in conjunction with the pressure expandable stent 66, the inner tube 24 thereof is typically modified to include an inflatable balloon 68 or other pressure exerting element mounted on the distal portion 38 of the inner tube 24, between the distal and proximal radiopaque markers 34, 36. In this respect, the pressure expandable stent 66 is positioned over the deflated balloon 68, and is then positioned within the lumen 20 of the outer tube 14, as seen in Figure 2. As seen in Figure 4a, subsequent to the positioning of the radiopaque marker 22 at the desired location relative to the intended implantation site, the stent 66 is exposed by either i) a distal advancement and elongation of the inner tube (see Figures 6 and 6a) or ii) proximal retraction and shortening of the outer tube 14 (see Figures 8 and 8a), such that the sleeve 40 is distally everted and drawn taunt, with the proximal radiopaque marker 36 of the inner tube 24 located a spaced distance beyond the radiopaque marker 22 of the outer tube 14.

When the distal portion 38 bearing the stent 66 is deployed in the previously described manner, reference is made to the distal and proximal radiopaque markers 34, 36 to insure the proper orientation of the stent 66 relative to the treatment site. Thereafter, the balloon 68 is inflated, thus facilitating the radial expansion of the stent 66 into contact with the luminal surface of the anatomical passage. The balloon 68 is then deflated, with the distal portion 38 then being proximally drawn back into the lumen 20 by the proximal movement of the inner tube 24 relative to the outer tube 14 accomplished by pulling the inner body 60 of the proximal connector assembly 46 (with the knob member 56 being loosened) while tightly grasping the outer body 48 thereof.

Embodiments of the Delivery Catheter

Having Elongateable/Retractable Inner Tube

Referring now to Figure 6, the delivery catheter 10 of the present invention may alternatively be configured to incorporate an inner tube 24a having a proximal end 26a which is attached to the outer tube 14 such that the guide wire lumen 30a of the inner tube 24a communicates with the outer surface of the outer tube 14. As will be recognized, if the inner tuber 24a is incorporated into the delivery catheter 10, the proximal connector assembly 46 will have a modified configuration, with only the proximal end of the outer tube 14 being attached thereto.

Though not shown, the distal region of the inner tube 24a is identically configured to that of the previously described inner tube 24, and includes a distal portion defined between distal and proximal radiopaque markers, with the distal portion being adapted to have a self-expanding stent positioned thereupon, or being provided with an inflatable balloon for use with a pressure expandable stent. Additionally, the opposed ends of a flexible sleeve are attached to and extend between the outer tube 14 and the inner tube 24a in the same manner as previously described in relation to the sleeve 40 and outer and inner tubes 14, 24.

When the delivery catheter 10 incorporates the inner tube 24a, the deployment of either a self-expanding stent or a pressure expandable stent from within the lumen 20 of the outer tube 14 is facilitated by the distal advancement of the distal portion of the inner tube 24a from the distal end 18 of the outer tube 14. Since the proximal end 26a of the inner tube 24a is rigidly secured to the outer tube 14, such distal advancement is accomplished by providing the inner tube 24a with an expandable region 70 preferably having a bellows-like configuration. In this respect, when the lumen 20 of the outer tube 14 is pressurized with the fluid, distally directed fluid pressure is exerted against the sleeve, thus causing the longitudinal stretching of the expanded

region 70. Such stretching of the expanded region 70 allows the inner tube 24a to move distally relative to the outer tube 14, and thus facilitates the distal advancement of the distal portion of the inner tube 24a from the distal end 18 of the outer tube 14. The expandable region 70 is preferably sized such that when fully stretched, the distal portion of the inner tube 24a bearing the stent is completely removed from within the lumen 20 of the outer tube 14.

Referring now to Figure 6a, as an alternative to the inner tube 24a, the delivery catheter 10 may be provided with an inner tube 24b. The inner tube 24b comprises a tubular outer sleeve 72 having a proximal end 74 and a distal end 76. The proximal end 74 of the outer sleeve 72 is rigidly secured to the outer tube 14 such that the lumen 78 of the outer sleeve 22 communicates with the outer surface of the outer body 14. In addition to the outer sleeve 72, the inner tube 24b includes a tubular inner sleeve 80 having a proximal end 82 and a distal end. Though not shown, the distal region of the inner sleeve 80 is identically configured to the distal region of the inner tube 24.

In the inner tube 24b, the proximal end 82 of the inner sleeve 80 is disposed within the lumen 78 of the outer sleeve 72 and slidably movable therewithin. The inner sleeve 80 itself defines a lumen 84 which communicates with the lumen 78 of the outer sleeve 72 when the outer and inner sleeves 72, 80 are slidably attached to each other in the aforementioned manner. Importantly, when the lumen 20 of the outer tube 14 is pressurized with the fluid, the distally directed pressure exerted against the sleeve results in the sliding movement of the inner sleeve 80 distally relative to the outer sleeve 72. Such distal movement of the inner sleeve 80 facilitates the distal advancement of the distal portion thereof from the distal end 18 of the outer tube 14. The overlap between the outer and inner

sleeves 72, 80 is sized such that the inner sleeve 80 may be distally moved relative to the outer sleeve 72 in an amount sufficient to facilitate the complete removal of the distal portion of the inner sleeve 80 bearing the stent from within the lumen 20 of the outer tube 14.

Embodiments of the Delivery Catheter Having Elongateable/Retractable Outer Tube

An alternative embodiment of the preferred delivery catheter 10 is shown in Figures 8a and 8b. This alternative embodiment comprises an elongate pliable outer tube 14a which has a collapsible segment 90. The collapsible segment 90 of the outer tube 14a may be formed of a plastic film or membrane bonded to separate segments of the outer tube 14a, or as shown in the drawings may comprise a portion of the outer tube 14a which has been drawn or otherwise reduced to a wall thickness which is narrower than that of the remainder of the outer tube 14a so as to permit folding or pliability of that collapsible segment 90. Scored regions, living hinges or relatively pliable areas may be formed at discrete locations in the collapsible segment 90 to cause the collapsible segment 90 to longitudinally collapse or fold in a zig-zag (e.g., "accordion") manner, as shown in Figure 8b.

The inner tube 24 of this alternative embodiment is a continuous, non-telescoping, non-collapsible tubular member having a proximal end anchored to the outer tube 14a at the side opening 26 and a distal end whereupon the stent 12 is mounted.

Depending on the relative structural integrity and rigidity of the collapsible segment 90 of the outer tube 14a, it may be desirable to provide an optional stiffening member 92, such as a wire, within the lumen 20a of the outer tube. Such stiffening member 92 will be disposed within the lumen 20a of the outer tube 14a when this alternative embodiment of the catheter 10 is in its initial configuration shown in Figure 8a, wherein the

stent 12 is positioned within the lumen 20a of the outer tube 14a. The stiffening member 92 will prevent the outer tube 14a from bending or sagging in the region of the collapsible segment 90 when the outer tube 14a is in its elongated configuration shown in Figure 8a. Thereafter, when negative pressure is applied to the lumen 20a of the outer tube 14a so as to draw the outer tube 14a to its longitudinally contracted state shown in Figure 8b, the stiffening wire may optionally be removed or retracted as the collapsible segment 90, when in such collapsed configuration shown in Figure 8b, will be less likely to undergo inadvertent bending or sagging.

Thus, when the embodiment shown in Figures 8a and 8b is used, the stent 12 will be initially mounted on the distal portion of the inner tube 24 and, thereafter, positive pressure will be applied to the lumen 20a of the outer tube 14a so as to cause the collapsible segment 90 of the outer tube 14a to assume its extended configuration. Due to the fact that the inner tube 24 is of fixed length with its proximal end being soundly anchored and attached to the body of the outer tube 14a, such application of positive or increased pressure to the lumen 20a of the outer tube 14a will cause the distal portion of the outer tube 14a to advanced over and fully surround the distal portion of the inner tube 24 whereupon the stent 12 is mounted. Concurrently, the flexible sleeve 40 will assume an inverted position within the lumen 20a of the outer tube 14a, as shown in Figure 8a.

With this embodiment of the catheter device 10 disposed in the configuration shown in Figure 8a, the proximal end of a prepositioned guide wire 32 may be inserted into the distal end of the inner tube lumen 26, and the catheter may then be advanced over such prepositioned guide wire 32 until the stent 12 becomes located at its desired implantation site, as evidenced by

radiologic visualization of the markers 34 and 36 located at either end of the stent 12.

Thereafter, the pressure within the lumen 20a of the outer tube 14a is decreased (e.g., by application of suction to the lumen 20a), so as to draw the outer tube 14a to a longitudinally contracted or shortened length wherein the collapsible segment 90 is fully collapsed (e.g., folded, compressed) as shown in Figure 8b. Such shortening of the outer tube 14a causes the distal end of the outer tube 14a to retract in the proximal direction, thereby exposing the stent 12 and causing the sleeve 40 to become everted, as shown in Figure 8b. In embodiments wherein the stent 12 is of the pressure expandable variety, a balloon inflation fluid or other force will then be used to exert outward radial pressure against the stent 12 to radially expand and plastically deform the stent such that it will remain into contact with the surrounding luminal surface. In other embodiments wherein the stent 12 is of the self-expanding variety, the mere removal of the outer tube 14a from the area surrounding the stent 12 will allow the stent 12 to self-expand to its desired radially expanded configuration in which it will contact and engage the luminal surface of the surrounding blood vessel wall.

A Roll-Up Stent Device of the Present Invention

Referring now to Figures 7 and 7a, as previously explained, the delivery catheter 10 of the present invention is preferably used in conjunction with the self-expanding stent 12. The stent 12 is of a metallic design, and is fabricated by milling or chemically etching a rectangularly configured, thin-walled sheet 86 to include a desired pattern of elongate slots 88, each of which has a longitudinal axis. The preferred pattern of the slots 88 consists of a series of rows of rectangular slots, with the longitudinal axes of the slots 88 in each row being linearly aligned with each other and extending in parallel relation to the

longitudinal axes of the slots 88 in the remaining rows. The sheet 86 has a preferred thickness of from approximately 0.0005 inches to 0.004 inches. Subsequent to the slots 88 being formed therein, the sheet 86 is rolled longitudinally into the tubular shape shown in Figure 7a. The pattern of the slots 88 within the sheet 86 will typically be varied according to the intended application of the stent 12. In this respect, the pattern of the slots 88 shown in Figure 7 is preferred when the stent 12 is to be used in relation to blood flow applications since, as seen in Figure 7a, the longitudinal axes of the slots 88 will be parallel to the direction of blood flow when the stent 12 is operatively positioned, thus promoting laminar blood flow therethrough. The sheet 86 may be fabricated from a radiopaque material, or may have radiopaque markers embedded therein.

As previously indicated, in addition to the self-expanding stent 12 and the pressure expandable stent 66, the delivery catheter 10 may be used in conjunction with other stent designs. Such alternative stent designs include those stents fabricated from shape memory materials. Additionally, the pressure expandable or self-expanding stents with which the delivery catheter 10 is utilized may be fabricated from wire, flat wire, or various other materials.

The delivery system constructed in accordance with the present invention provides numerous advantages over stent delivery systems known in the prior art. In prior art delivery systems, a sheath must be manually moved relative to a delivery catheter to facilitate the deployment of the stent. As such, the materials of the sheath and the delivery catheter must be thick walled and/or stiff. Such designs result in the catheter delivery system being too stiff or bulky to be effectively used in small vessels and/or tortuous anatomical passageways. The present delivery system uses

fluid pressure to deploy the stent from the delivery catheter. As such, the stent deployment using the present delivery system is conducted in a much more controlled manner, with the present design allowing for the use of very thin-walled and flexible materials for the outer and inner tubes 14, 24. The use of such materials results in a delivery system that is smaller and significantly more flexible than those known in the prior art.

Additional modifications and improvements of the present invention may also be apparent to those skilled in the art. Thus, the particular combination of parts described and illustrated herein is intended to represent only certain embodiments of the present invention, and is not intended to serve as limitations of alternative devices within the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A delivery catheter for delivering a radially expandable intraluminal apparatus to a desired location within a body lumen, said catheter comprising:

a) an outer tube having a proximal end, a distal end, and a lumen extending longitudinally therethrough;

b) an inner tube having a proximal end, a distal end, and a lumen extending longitudinally therethrough, the proximal end of said inner tube being attached to the outer tube, said inner tube having a distal portion upon which the intraluminal apparatus may be mounted; and

c) a flexible sleeve having a first end attached to a distal portion of the outer tube and a second end attached to the inner tube at a location which is proximal to said distal portion of said inner tube, said sleeve forming a substantially fluid-tight seal between said inner tube and said outer tube such that the pressure within the lumen of the outer tube and surrounding said inner tube may be volitionally increased and decreased;

d) at least one of said outer tube and said inner tube being of variable length, such that in response to changes in the pressure within the lumen of the outer tube, the delivery catheter will transition between:

a first configuration wherein the distal portion of the inner tube is surrounded laterally by the outer tube; and

a second configuration wherein the distal portion of the inner tube is not surrounded laterally by said outer tube.

2. The delivery catheter of Claim 1 wherein said outer tube is of fixed length and said inner tube is of variable length such that, when the pressure within the lumen of the outer tube is increased while the catheter

is in its first configuration, the inner tube will lengthen and the flexible deployment sleeve will evert, thereby causing the catheter to assume its second configuration.

3. The delivery catheter of Claim 2 wherein the variability in length of the inner tube is by way of a collapsible segment of the inner tube such that the inner tube is initially deployable in a longitudinally shortened state wherein said collapsible portion is collapsed, and is subsequently transitionable to a longitudinally extended state wherein said collapsible portion is extended.

4. The delivery catheter of Claim 3 wherein the collapsible segment of the inner tube is a telescoping segment formed of an inner tube portion and an outer tube portion, at least one of said inner and outer tube portions being axially slidable relative to the other, in telescoping fashion.

5. The delivery catheter of Claim 3 wherein the collapsible segment of the inner tube is a pliable segment capable of folding to a longitudinally shortened state.

6. The delivery catheter of Claim 1 wherein said inner tube is of fixed length and said outer tube is of variable length, such that when the pressure within the lumen of the outer is decreased while the catheter is in its first configuration, the outer tube will shorten and the flexible sleeve will evert, thereby causing the catheter to assume its second configuration.

7. The delivery catheter of Claim 5 wherein the variability in length of the outer tube is by way of a collapsible segment formed in the outer tube, said collapsible segment being initially deployable in a longitudinally elongated configuration wherein the outer tube is a first length, and being subsequently transitionable to a longitudinally shortened configuration wherein said outer tube is of a second

length, said second length being shorter than said first length.

8. The delivery catheter of Claim 7 wherein the collapsible segment of the outer tube is a telescoping segment formed of an inner tube portion and an outer tube portion, at least one of said inner and outer tube portions being axially slidable relative to the outer, in telescoping fashion.

9. The delivery catheter of Claim 7 wherein the collapsible segment of the outer tube is a pliable segment capable of folding to a longitudinally shortened state.

10. The delivery catheter of Claim 1 wherein said outer tube includes a radiopaque marker attached to the distal end thereof.

11. The delivery catheter of Claim 10 wherein the first end of the sleeve is rigidly captured between said radiopaque marker and said outer tube.

12. The delivery catheter of Claim 1 wherein said inner tube includes a distal radiopaque marker attached to the distal end thereof and a proximal radiopaque marker attached thereto at a location proximal to the distal end thereof, the distal portion of the inner tube being defined between the distal and proximal radiopaque markers.

13. The delivery catheter of Claim 12 wherein the second end of the sleeve is rigidly captured between the proximal radiopaque marker and the inner tube.

14. The delivery catheter of Claim 1 further comprising an inflatable balloon disposed on the distal portion of the inner tube.

15. The delivery catheter of Claim 1 further comprising a proximal connector assembly attached to the proximal ends of the inner and outer tubes, said proximal connector assembly comprising:

a) a tubular outer body defining proximal and distal ends, the proximal end of the outer tube being attached to the distal end of the outer body;

b) a knob member rotatably connected to the proximal end of the outer body;

c) a tubular inner body defining proximal and distal ends, said inner body extending through the knob member and into the outer body, the proximal end of the inner tube being attached to the distal end of the inner body; and

d) an elastically deformable sealing member disposed between the inner and outer bodies;

e) said knob member being cooperatively engaged to the sealing member such that the rotation of the knob member in a first direction causes compressive pressure to be applied to the inner body by the sealing member which prevents the movement of the inner and outer tubes relative to each other, and the rotation of the knob member in a second direction opposite the first direction discontinues the application of compressive pressure to the inner body by the sealing member which permits the movement of the inner and outer tubes relative to each other.

16. The delivery catheter of Claim 15 wherein said outer body of the proximal connector assembly includes a tubular side arm portion which fluidly communicates with the lumen of the outer tube.

17. A system for implanting a radially expandable intraluminal apparatus within a body lumen, said system comprising the delivery catheter of Claim 1 in combination with a radially expandable intraluminal apparatus mounted on the distal portion of the inner tube, distal to the site at which the distal end of the sleeve is attached to the inner tube.

18. A method for delivering a radially expandable intraluminal apparatus to a desired site within a body lumen, said method comprising the steps of:

a) an outer tube having a proximal end, a distal end, and a lumen extending longitudinally therethrough;

b) an inner tube having a proximal end, a distal end, and a lumen extending longitudinally therethrough, the proximal end of said inner tube being attached to the outer tube, said inner tube having a distal portion upon which the intraluminal apparatus may be mounted; and

c) a flexible sleeve having a first end attached to a distal portion of the outer tube and a second end attached to the inner tube at a location which is proximal to said distal portion of said inner tube, said sleeve forming a substantially fluid-tight seal between said inner tube and said outer tube such that the pressure within the lumen of the outer tube and surrounding said inner tube may be volitionally increased and decreased;

d) at least one of said outer tube and said inner tube being of variable length, such that in response to changes in the pressure within the lumen of the outer tube, the delivery catheter will transition between:

a first configuration wherein the distal portion of the inner tube is surrounded laterally by the outer tube; and

a second configuration wherein the distal portion of the inner tube is not surrounded laterally by said outer tube.

and,

a radially expandable intraluminal apparatus mounted on the distal portion of the inner tube;

b) with the catheter disposed in its first configuration, inserting the catheter into a mammalian body such that the distal end of the catheter is located at a desired location within a body lumen;

c) changing the pressure within the lumen of the outer tube of the delivery catheter so as to cause the delivery catheter to transition to its second configuration; and

d) causing the intraluminal apparatus to radially expand into contact with the body lumen, and to become separated from the delivery catheter.

19. The method of Claim 18 further comprising the step of:

e) subsequently changing the pressure within the lumen of the outer tube to cause the delivery catheter to return its first configuration.

20. The method of Claim 19 further comprising the step of:

f) removing the delivery catheter from the body, while the intraluminal apparatus remains implanted within the body lumen.

21. The method of Claim 18 wherein the delivery catheter provided in step a, has an outer tube of variable length and an inner tube of fixed length, and wherein the change in pressure accomplished in step c of the method is a decrease in pressure.

22. The method of Claim 18 wherein the delivery catheter provided in step a has an outer tube of fixed length and an inner tube of variable length, and wherein the change in pressure accomplished in step c is an increase in pressure.

23. The method of Claim 21 wherein the delivery catheter provided in step a, which has an outer tube of variable length and an inner tube of fixed length, further comprises a stiffening element which is at least temporarily deployable within the outer tube to prevent

the outer tube from undergoing unwanted deformation while the delivery catheter is in its first configuration.

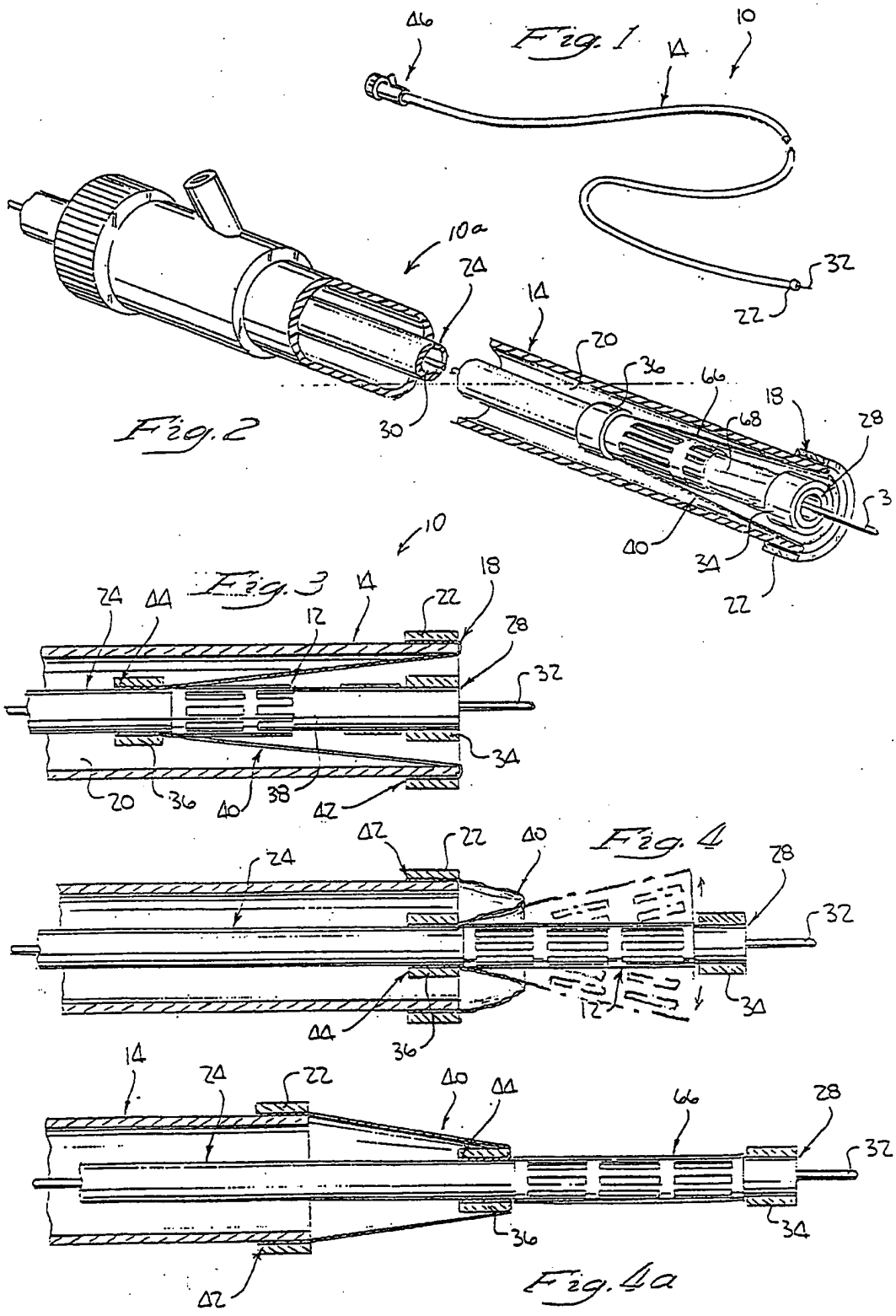


Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 4a

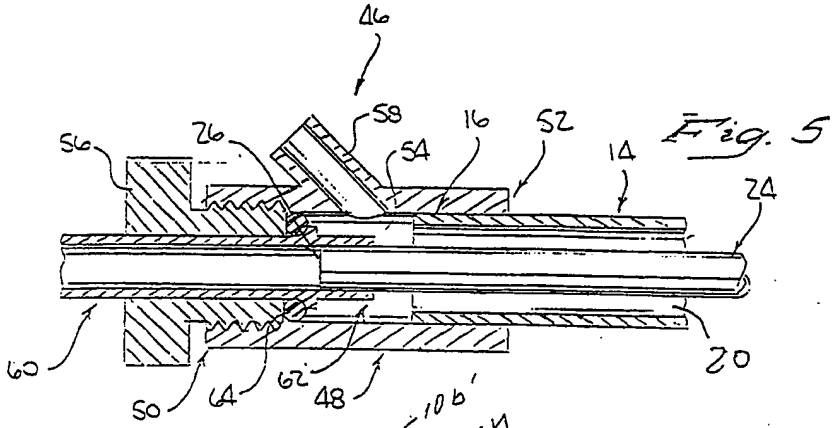


Fig. 5

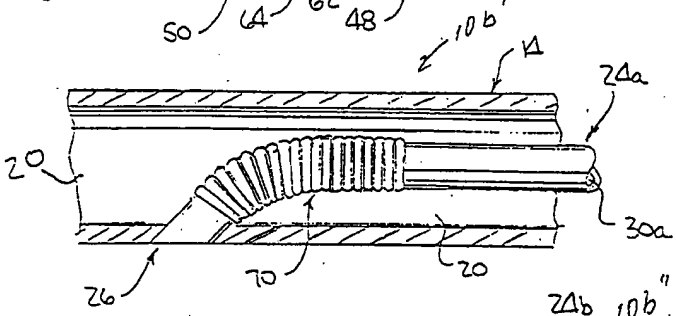


Fig. 6

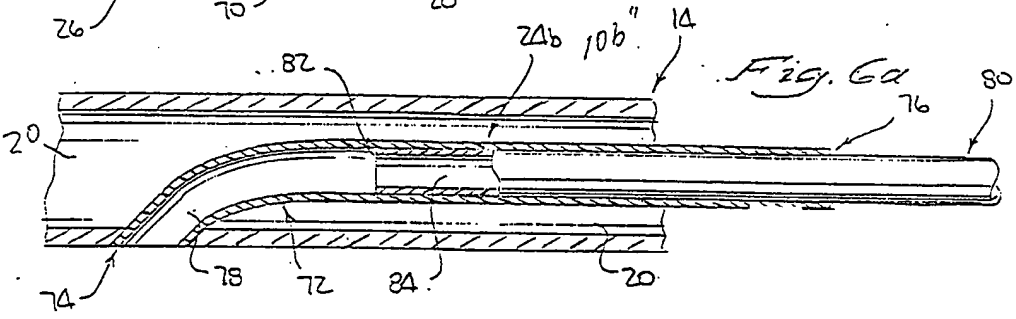


Fig. 6a

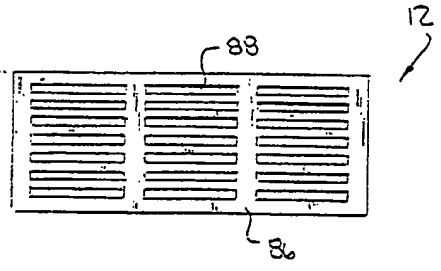


Fig. 7

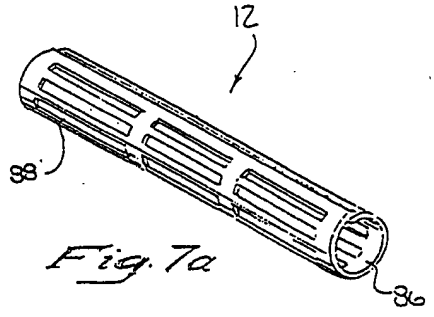
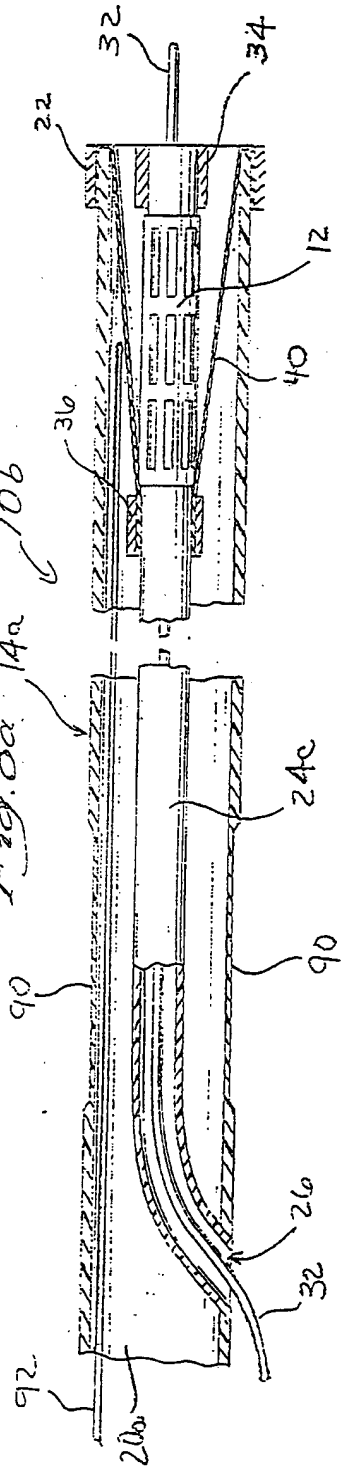


Fig. 7a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14a
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26
32
92
20a

Fig. 8a

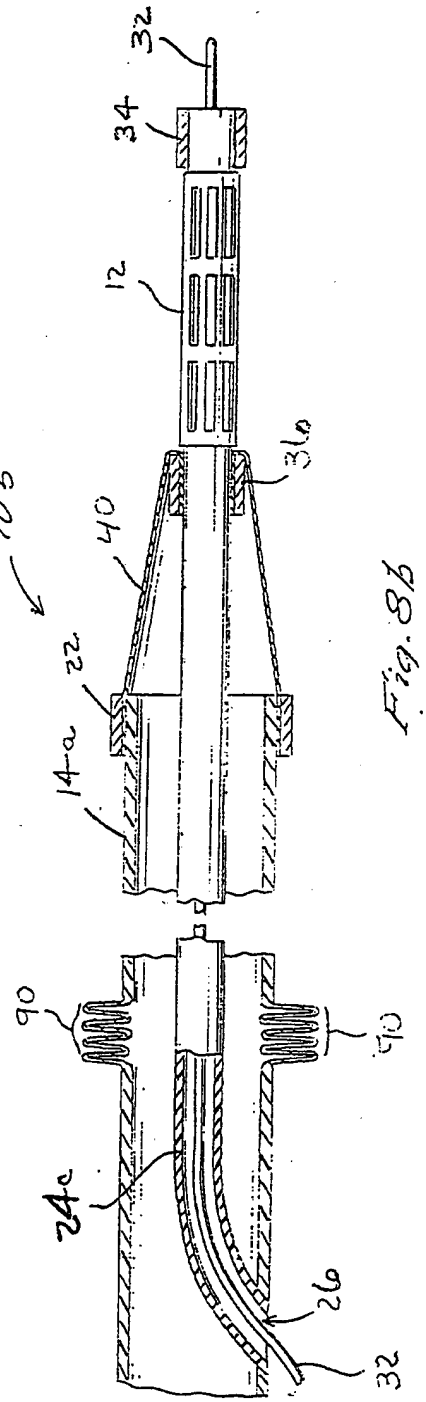
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Fig. 8b

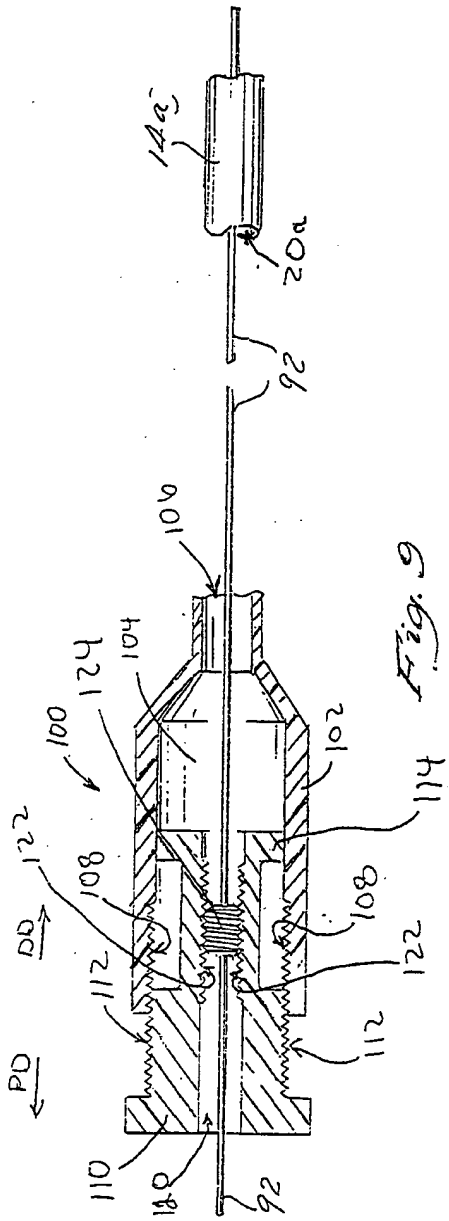

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/12822

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00
US CL :604/271; 606/108

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/271; 606/108

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,732,152 A (WALLSTEN et al.) 22 March 1988, entire documwnt.	1-23
A	US 4,848,343 A (WALLSTEN et al.) 18 July 1989, entire document.	1-23
A	US 4,863,440 A (CHIN) 05 September 1989, entire document.	1-23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
27 AUGUST 1998	23 SEP 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL THALER Telephone No. (703) 308-2981

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